19 FEDERAL REPUBLIC OF GERMANY

12 Disclosure
11 DE 38 07 944 A 1

51 IPC CL.4:
A 61 M 25/02
A 61 M 5/14

[seal]

German Patent Office

21 File No.: P 38 07 944.5
22 Registration Date: March 10, 1988
43 Disclosure Date: September 21, 1989

==========

Property of the Authorities

==========

71 Applicant:
B. Braun Melsungen AG,
3508 Melsungen (DE)

72 Inventors:
Haack, Karl Werner an, 4600 Dortmund, (DE);
Haindl, Hans-Günther, Dip.-Ing. Dr. med.;
Boxberger, Michael, Dipl.-Chem. Dr.rer.nat.,
3508 Melsungen (DE)

74 Representatives:
Schönwald, K.,Dr.-Ing.;
von Kreisler, A., Dipl. -Chem.;
Fues, J., Dipl.-Chem. Dr. rer.nat.;
Selting, G., Dipl.-Ing.;
Werner, H., Dipl.-Chem. Dr. rer. nat.
Böckmann gen. Dallmeyer, G., Dipl.-Ing.,
Patent Lawyers, 5000 Cologne

Patent application has been submitted according to § 44 Pat. Law

54 Device for fastening a catheter or a cannula on the skin surface

The essential feature of the device for fastening a catheter (10) on the skin surface is the formation of a hole (17) in a lower plaster (11) onto which an upper plaster (12) can be stuck. The hole (17) is positioned over a puncture site (22) for insertion of a catheter (10) in the tissue, so that the puncture site (22) can be visually checked after lifting the upper plaster (12). A plug of foamed material impregnated with a bactericidal substance (21) projects through the hole (17) in the lower plaster (11) and onto the section (10a) of the catheter (10) which emerges from the puncture site (22), protecting it from bacterial invasion.

Description

The invention is a device for fastening a catheter or a cannula to the surface of the skin, consisting of a lower and an upper plaster, each of which has an adhesive layer. The safeguarding of the external end of the catheters and of the cannulae which protrudes from the body once having been inserted through a puncture in the tissue into a body cavity such as a blood vessel, is mandatory in order to prevent dislocations, bending or the cutting in of the catheter and so that the lumen of the catheter is entirely available for the unimpeded flow of the liquid. To fasten the catheter to the skin an adhesive plaster is used in the simplest cases. However, it then becomes laborious, if the catheter has intentionally to be relocated, in that the adhesive material once necessary for the secure fastening to the skin, has to be removed, the catheter then has to be removed from the adhesive plaster and then the catheter hose has to be secured once again to the skin of the patient. Furthermore, it is a common practice to wind a surgical thread several times around the catheter at the site where it exits the skin and then to sew same to the skin. Hereby one runs a greater risk that the catheter is cut by the relative sharp thread in the knotting process or later by the pulling and moving by the patient, and that the section of the catheter in the vessel is flushed into the heart by the circulating blood, leading to a life-threatening situation.

In order to improve the attaching of a catheter to the skin surface, a clip of two clamping plates was created (DE-GM 82 04 827), which show clamping elements for attaching the catheter tubes which can either be stitched onto the skin or stuck to the skin by means of adhesive tape. The application and attaching of such clips is an onerous task. Different types of clips with clamping elements of different width must be produced and kept in stock for catheters of various diameters, and these clips do not provide any protection against bacterial contamination at the puncture site.

In order to prevent any bacterial contamination, 0.2 µm bacteria retentive filters are used in the infusion therapy. However, such filters can only offer protection against the growth of germs in the interior of the infusion device. Of a far grater clinical significance, however, is the entry of pathogens, especially of skin pathogens at the puncture site. Even if catheters are meticulously cared for, the transmission of germs along the outside of the catheter is not completely preventable. Therefore, in the well-known fixing system of the type initially mentioned (DE-OS 36 43 985) the provision is made for the lower plaster to be covered by a bactericidal substance on one or both sides. In this familuar procedure the lower plaster is first fastened to the surface of the skin. Then this lower plaster is punctured using a sharp steel cannula, and finally the steel cannula, or the catheter tube that has been inserted by means of the steel cannula, and once this steel cannula has been removed, is then sealed around the point of puncture by means of an adhesive that is impermeable to bacteria. In the next step, the upper plaster is fastened over the puncture and sealing site. This procedure is risky, since while the lower plaster is being punctured, particles are cut out, which can then enter the bloodstream. Furthermore, the puncture point can only be checked after the lower plaster has been removed from the surface of the skin, disturbing the catheter at its point of exit from the skin. Consequently there is

the danger that, in order to avoid trauma and contamination, the site is seldom checked, although a repeated examination of the puncture site ought to occur, especially of those catheters left in place for an extended period of time.

The purpose of the invention is to create a simply handled device for fastening a catheter or a cannula in such a way, as to make visual examinations of the puncture site easily possible.

OS 38 07 944

The invention solves this problem by providing a hole in the lower plaster.

In this way the lower plaster can be attached over the catheter or a cannula which have been fed into the tissue and are lying flat on the surface of the skin in such a way, that the hole is directly over the puncture point, and so that upon separating the upper plaster from the lower one, the puncture point becomes visible and can be examined. Afterwards the upper plaster can once again be attached to the lower one and the puncture point is sealed once more. During this procedure the catheter remains in position under the lower plaster and does not change its location at the point of exit from the skin. It is also easy on the tissue. A flexible catheter exiting from the puncture point can be placed in the shape of a U so that the plaster attached over it fastens two essentially parallel sections of the catheter to the surface of the skin. Thereby one minimizes the danger of strangling the catheter at the exit point, and the double fastening is more secure.

The fact that the upper plaster is provided with a rubber-like elastic plug which fits into the hole of the lower plaster and that the lower plaster has a layer of foam of the same thickness as the plug, is an advantage. The lower surface of this elastic plug on the upper plaster which sits in the hole, presses on the catheter or the cannula at the puncture site and holds it firmly in position without strangling it. In addition, this rubber-like elastic plug can also function as a means of avoiding bacterial contamination at the puncture site. For this purpose the plug is impregnated with a bactericidal agent which has a long-term effect on the puncture site. Especially suitable for this function are Chlorhexidin, Poly(1-vinyl-2pyrrolidon)-iodine, colloidal silver or silver ions, preferably silver chloride or silver nitrate in combination with a matrix, preferably with polyethylenglycol, gelatin, collagen or Elektrodengel. The plug is in effect a reservoir of the agent which prevents germs, especially skin pathogens, from entering at the puncture site.

The best version of the invention the upper plaster shows a flat foil to which the plug has been fastened, which at the edge is, like a hinged lid, in contact with the foamed layer of the lower plaster. The result is one single unit consisting of an upper and a lower plaster, which simplifies handling the device. The adhesive material on the upper foil is such, that a repeated process of removing and refastening of the upper plaster is possible, so that the puncture site can be repeatedly examined without compromising the effective seal of the upper plaster. In this process the elastic plug can each time be newly saturated with a bactericidal substance.

The diagram depicts a schematic illustration of the invention.

Shown are:

Fig. 1, a perspective view of the device as it is applied to the surface of the skin in the open position

Fig. 2, a longitudinal section of the device as shown in Fig. 1 in the closed position

The device for the purpose of fastening the external section of a cannula or of a flexible catheter 10 on the surface of a patient's skin consists mainly of a rectangular lower plaster 11 of which one side edge 13 has been connected to a rectangular upper plaster 12 of the same size so that it can be opened and closed.

OS 38 07 944

The lower plaster 11 has a layer of foamed material 15 which has an adhesive material 15 over the entire surface on the underside. It has a circular cylindrical hole 17 preferably in one of the transverse halves of the lower plaster 11 on the longitudinal mid-line, which penetrates the foam layer 15 as well as the adhesive layer 16 and which is open at both ends.

The upper plaster 12 consists of a foil 19 of much less thickness than the foamed layer 15 of the lower plaster 11. This foil 19 is securely joined to the foamed layer 15 at the side edge of the device 13 behind a folding line 23. At the opposite side edge the foil 19 is a little bit longer 20 so that it can be easily grasped. The underside of the foil 19, with the exception of the tab 20 and of the side edge 13, is covered with a self-adhering adhesive to the smooth upper surface of the foamed material 15 of the lower plaster 11. The composition of the adhesive 18 is such, that a repeated opening and closing is possible. A circular cylindrical plug 21 has been fastened to the adhesive layer 18. The depth of the plug 21 is equal to the thickness of the foamed layer 15, and its shape and dimensions conform with the hole 17, so that if the device is in the closed position, the plug 21 protrudes through the hole 17 and fills it. The plug 21 is made of soft foamed material. It is saturated with a long-acting bactericidal substance.

The flexible catheter tube 10 is threaded, for example, into a blood vessel through the puncture point 22 in the usual manner once the skin has been punctured, and is held in place in the shape of a U. Then the lower plaster is stuck onto the two sections 10a and 10b of the catheter 10 in the manner depicted in Fig. 1, after the protective cover has been removed from its adhesive layer. The lower plaster 11 is fastened so that its hole 17 is over the puncture point 22 and the two catheter sections are fixed in place parallel to each other. As shown in Fig. 2, the layer of foam 15 is somewhat depressed by section 10b of the catheter 10. The density of the foamed material for the foam layer 15 is chosen so that the foam gives way even to the pressure of very thin-walled, flexible catheters 10 and therefore is not limiting the catheter lumen. The foamed material of the plug 21, which protrudes through the hole 17 of the lower plaster 11 and is lying against the upper side of the catheter 10 at the puncture point 10,

must have the same property. The device is supplied with the lower and upper plasters 11, 12 folded together and also in a sterile package. To put it in place onto a positioned catheter 10, the protective layer is pulled off the adhesive layer 16, and the upper plaster 12 is lifted up a bit from the lower plaster 11, in order to be able to see the puncture point 22 through the hole 17 of the lower plaster, so as to be able to apply the lower plaster 11 with the hole 17 precisely over the puncture point 22.

For the purpose of examining the puncture point 22, the upper plaster 12 can be pulled up as far as the folding line 23 as often as necessary and can then again be refastened to the lower plaster 11, so that the puncture point is tightly closed by the plug.

Patent Requirements

1. A device for the purpose of fastening a catheter (10) or a cannula on the skin surface, consisting of a lower plaster (11) and an upper plaster (12), each having an adhesive layer (16, 18), distinguished by the fact that there is a hole (17) in the lower plaster (11).
2. A device as in requirement 1., distinguished by the fact that the upper plaster (12) bears a rubber-like elastic plug (21) which fits into the hole (17) of the lower

plaster (11), and that the lower plaster ((11) has a layer of foamed material (15) which essentially is of the same depth as the plug (21).
3. A device as in requirement 1. or 2., distinguished by the fact that the plug (21) does contain a bactericidal active agent.
4. A device as in one of the requirements 1. to 3., distinguished by the fact that the upper plaster (12) is a flat foil (19) to which the plug (21) has been attached and which at one edge (13) is connected to the foam layer (15) of the lower plaster (11), so that it can be folded back and forth.

Number:	38 07 944
IPC CL.4:	A 61 M 25/02
Registration Date:	March 10, 1988
Disclosure Date:	September 21, 1989